

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
GREGORY L. BRADLEY, ESQUIRE  
MEDRAD, INC.  
ONE MEDRAD DRIVE  
INDIANOLA, PA 15051

# PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

|  |  |  |
|--|--|--|
| Applicant's or agent's file reference<br>IN/04-002 PC  |  | Date of mailing<br>(day/month/year) <b>14 OCT 2005</b>                   |
| International application No.<br>PCT/US05/07829  |  | International filing date (day/month/year)<br>11 March 2005 (11.03.2005) |
| International Patent Classification (IPC) or both national classification and IPC<br>IPC(7): A61B 5/00 and US Cl.: 600/583 |  | Priority date (day/month/year)<br>11 March 2004 (11.03.2004)             |
| Applicant<br>MEDRAD, INC.  |  |  |

1. This opinion contains indications relating to the following items:

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☐ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

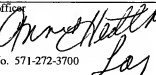
## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

|  |  |  |
|--|--|--|
| Name and mailing address of the ISA/ US<br>Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, Virginia 22313-1450<br>Facsimile No. (703) 305-3230 | Date of completion of this opinion<br>10 September 2005 (10.09.2005) | Authorized officer<br>Brian Szma <br>Telephone No. 571-272-3700 |
|--|--|--|

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/07829

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US05/07829

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

|                               |                                   |     |
|-------------------------------|-----------------------------------|-----|
| Novelty (N)                   | Claims <u>1-29,32,35-41,43-56</u> | YES |
|                               | Claims <u>30,31,33,34,42</u>      | NO  |
| Inventive step (IS)           | Claims <u>1-29,32,35-41,43-56</u> | YES |
|                               | Claims <u>30,31,33,34,42</u>      | NO  |
| Industrial applicability (IA) | Claims <u>1-56</u>                | YES |
|                               | Claims <u>NONE</u>                | NO  |

**2. Citations and explanations:**

Claims 30, 31, 33, 34 and 42 lack novelty under PCT Article 33(2) as being anticipated by Rizoju et al (6,669,685 B1).

Claims 1-29, 32, 35-41 and 43-56 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a penetrator positioned within the passage, the penetrator being energized in a repetitive manner to assist in penetrating tissue; a penetrator in operative connection with the catheter, the penetrator being energized in a repetitive manner to assist in penetrating tissue; the actuator adapted to cause motion of the first effector such that tearing of tissue takes place in regions where there is close proximity of tissue to the surface of the first effector; a second tubular structure positioned inside the first tubular structure, such that cut tissue passes into the second tubular structure and is protected from the effect of the rotational energy of the first tubular structure; a nonlinear penetrator comprising at a forward end thereof at least a first effector, the first effector being actuated to move; a penetrator at a forward end thereof at least a first effector, the effector being rotatable about the axis of the penetrator; a non-coring needle comprising a forward extending section comprising at least two points spaced from each other and adapted to pierce tissue; and a blunt needle comprising at least one effector that is energized to penetrate tissue.

Claims 1-56 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.